



Final Regulation Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 5 - 110
Regulation title	Immunization of School Children
Action title	Update of the Regulations for the Immunization of School Children
Date this document prepared	September 28, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The proposed amendment to existing regulations will ensure compliance with legislation enacted by the 2006 and 2007 General Assemblies and with current immunization practices as recommended by the Advisory Committee for Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians (required by the Code of Virginia).

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

Dr. Karen Remley, Commissioner, Virginia Department of Health, approved the final amendments to the Regulations for the Immunization of School Children on behalf of the State Board of Health on September 24, 2009.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Statutory authority to promulgate these regulations is granted to the State Board of Health by §§ 22.1-271.2 and 32.1-46 of the Code of Virginia.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Legislation enacted by the 2006 Virginia General Assembly requires the regulations for the immunization of school children to be updated to reflect current immunization recommendations. It also added two new required vaccines (Tetanus, diphtheria and acellular pertussis booster [Tdap] and pneumococcal vaccines). Legislation enacted by the 2007 Virginia General Assembly added an additional new vaccine requirement (human papillomavirus vaccine). The regulations must be amended to comply with the new legislation as well as with current immunization recommendations.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Amendments to the current regulations will:

- Update and clarify definitions;
- Update childhood immunizations required for attendance at Virginia schools and day cares to include additional required vaccines and reflect current recommended immunization practices;
- Add requirements for demonstrating existing immunity to varicella; and,
- Update responsibilities of admitting officials.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed regulations will ensure that children are protected to the extent possible from vaccine-preventable diseases and will indirectly protect the health of all citizens of Virginia. Disadvantages may include minimal increased costs associated with providing additional required vaccines. Compliance with the 6th grade Tdap requirement can be accomplished at the recommended 11-12 year old visit with the provider. The agency has reviewed the benefits and risks associated with these changes and agreed with the Advisory Committee on Immunization Practices' assessment that the benefits outweigh the risks associated with each change.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12 VAC 5-110-10	Conditional enrollment period for hepatitis B vaccine is defined as 180 calendar days	Clarified that the conditional enrollment period is 180 calendar days only if the student requires more than 2 doses of hepatitis B vaccine	As proposed, the definition could be misinterpreted to mean that 180 days would be allowed to complete vaccine series other than hepatitis B in certain situations.
12 VAC 5-110-10	Definition of school does not include family day care homes or developmental centers.	Added "any family day care home or developmental center" to the definition of "school".	Family day care homes and developmental centers are included in §32.1-46 but not in §22.1-271.1 of the Code. Regulatory authority covers these facilities and they should be added to the definition as requested by the Division of Licensing Programs.
12 VAC 5-110-50	Unchanged	Updated the Code citation for the Administrative Process Act	Recommended by the Attorney General's Regulatory Reform Commission
12 VAC 5-110-70	Diphtheria, tetanus, and pertussis vaccines indicate "four or more doses"	"or more" is removed for each vaccine type	"or more" is unnecessary; four is the minimum required for each vaccine
12 VAC 5-110-70	Minimum of 3 doses of polio vaccine required	Change the minimum number of doses to 4 and clarify that one dose must be administered on or after the 4 th birthday	Brings the Regulations into compliance with recent changes to the immunization schedule
12 VAC 5-110-70	Requirement for the 2 nd dose of measles, mumps, and varicella vaccine is at four to six years of age or	Removed the "four to six years of age" to clarify that the 2 nd dose of these vaccines must be administered prior to entering	As proposed, the requirement could be interpreted to mean that a child could attend

	prior to entering kindergarten	kindergarten	kindergarten without receiving these vaccines until the 6 th birthday.
12 VAC 5-110-90	Conditional enrollment period for hepatitis B vaccine is 180 calendar days	Clarified that the conditional enrollment period is 180 calendar days only if the student requires more than 2 doses of hepatitis B vaccine	As proposed, the definition could be misinterpreted to mean that 180 days would be allowed to complete vaccine series other than hepatitis B in certain situations.
12 VAC 5-110-100	Documentary proof for out-of-state students allows the record to be signed by a nurse	Clarified by adding "registered" that the nurse must be registered.	This change maintains consistency with other sections that specify registered nurse.
12 VAC 5-110-140	Unchanged	Deleted section	Recommended by the Attorney General's Regulatory Reform Commission

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Public Health Nurse, VDH/Richmond City Health District	Since pharmacists now provide some immunizations, has any consideration been given to listing licensed pharmacists, along with physicians, registered nurses, or health department officials as those who are authorized to give or verify immunizations given?	Pharmacists do not routinely provide all required vaccines to children and are not considered to be primary care providers. At this time, only influenza vaccine may be provided to minors when a prescriber is not physically present. The Regulations will remain as proposed.
School Health Specialist, Department of Education	The regulations as proposed may lead to confusion over exactly when the second dose of varicella, measles, or mumps vaccine is required. A child may enter kindergarten prior to turning six years of age but should have these vaccines prior to attending school. I suggest removing the "at four to six years of age or" in each section for those vaccines, simply stating "prior to entering kindergarten".	The Agency agrees that this can be confusing and has modified the proposed regulations accordingly.
School Health Specialist, Department of Education	It is possible that the conditional enrollment period for hepatitis B vaccine as currently defined could be misinterpreted. It is only when	The Agency agrees that this can be misleading and has modified the proposed regulations accordingly.

	<p>more than 2 doses of hepatitis B vaccine are required that students should be allowed more than the usual 90 days to complete the missing vaccination series. As currently written, this could be interpreted to mean that 180 days would be allowed to complete vaccine series other than hepatitis B.</p>	
<p>Representative, Virginia Nurses Association</p>	<p>VNA would respectfully request that you include the term, "registered" in 12VAC 5-110-100. We believe that the omission of "registered" is an inadvertent omission.</p>	<p>The Agency agrees and has made the proposed change.</p>
<p>Director, Division of Licensing Programs</p>	<p>The State Board of Social Services is responsible for developing regulations for licensed family day homes, voluntarily registered family day homes, and family day homes approved by family day systems. The Office of the Attorney General has advised that the Board does not have the legal authority to promulgate regulations requiring immunizations for children attending family day homes because that authority is specifically granted by § 32.1-46 (A) of the Code to the State Board of Health. The proposed Regulation does not address immunization requirements for attendance at family day homes. As a result of this omission in the proposed regulation, there is no requirement that children attending family day homes be adequately immunized. Section 32.1-46(A) of the code requires parents to have their children adequately immunized, but the Division of Licensing Programs has no authority to enforce that requirement for children attending licensed or regulated family day homes.</p>	<p>The Agency agrees and has modified the definition of "schools" to include any family day care home or developmental center.</p>

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-110-10			Clarify definitions (conditional enrollment to avoid misinterpretation, documentary proof, school, student, twelve months of age); add definition for immunization schedule
12 VAC 5-110-20			Add varicella, pneumococcal, and human papillomavirus disease as required by Code
12 VAC 5-110-30			Minor wording changes; no substantive changes
12 VAC 5-110-50			Update the Code citation as recommended by the Attorney General's Regulatory Reform Commission
12 VAC 5-110-70			Add requirement for spacing, minimum ages and minimum intervals for vaccine doses to be in accordance with the immunization schedule
			Separate DTaP vaccine into component antigens (diphtheria, tetanus, pertussis) as they appear in the Code; change minimum number of doses required for each from 3 to 4; add Code requirement for a booster dose at 6 th grade entry; renumber vaccines.
			Change minimum number of doses of polio vaccine required from 3 to 4
			Edit polio and measles vaccines for clarity; remove unneeded language
			Add requirement for a 2 nd dose of mumps vaccine as recommended by the current immunization schedule
			Edit Hib vaccine requirements for clarity
			Add language to allow 2 doses of hepatitis B vaccine rather than 3 when FDA approved schedule and vaccine is used
			Add varicella vaccine as required by Code and recommended by the immunization schedule
			Add pneumococcal vaccine as required by Code
			Add human papillomavirus vaccine (HPV) for girls prior to entry into 6 th grade as required by Code
12 VAC 5-110-80			Add web address; remove unnecessary language
			Add criteria for demonstration of existing immunity to varicella
			Add authority to exclude unimmunized children when outbreak is identified
			Add exemption criteria for HPV vaccine
12 VAC 5-110-90			Add documentation of existing immunity to the category of students considered to be

			adequately immunized
			Clarify conditional enrollment period
			Add activities required for homeless students
			Delete the Table, "A Suggested Plan for Ensuring Compliance"
			Add information to allow admitting officials to submit required reports using a web-based reporting system
			Add requirement for admitting officials to ensure parent or guardian of females to be enrolled in the 6 th grade receive educational materials describing HPV vaccine
12 VAC 5-110- 100			Edit criteria for documentary proof for out-of-state students
12 VAC 5-110- 130			Update and clarify parental responsibilities; add penalties
12 VAC 5-110- 140			Delete section as recommended by the Attorney General's Regulatory Reform Commission
FORMS			Update version of school entrance form

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The agency believes that the proposed amendment to the regulations is the least burdensome option to meet the requirements of the Code and comply with current immunization practices as recommended by the Advisory Committee for Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

Parents are required by the *Code of Virginia* to have their children immunized. The amended regulations add two recommended vaccines to the requirements and increase the doses of four others to more closely comply with current ACIP recommendations. The regulations allow exemptions for medical reasons or if immunizations conflict with religious beliefs. All required vaccines are available at no cost to parents at local health departments.